REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims.

Applicants have cancelled claims 25, 30, and 32 without prejudice or disclaimer.

Applicants have amended claims 21, 24, 28, and 44. Applicants have incorporated the subject matter of claim 25 into claim 24, and the subject matter of claims 30 and 32 into claim 28. Support for this amendment is found throughout the specification. Applicants submit that the amendments to the claims do not require a new search as the subject matter was already searched and that no issues are presented that were not previously considered by the Examiner.

Allowed claims

Applicants acknowledge that claims 1-10 and 13-20 are allowable.

Rejections Under 35 U.S.C. § 103(a)

The Examiner rejected claims 21-35 and 44-47 under 35 U.S.C. § 103(a) as being obvious over Freed et al. (U.S. Patent No. 5,891,185) in view of Sanders (U.S. Patent No. 5,897,579). Claims 25, 30 and 32 have been cancelled rendering the rejection of these claims moot. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

The recent Supreme Court case, *KSR Int 'I Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007), sets forth the legal standard for obviousness. This case reaffirms the analytical framework set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), which mandates that an objective obviousness analysis includes: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art. Id. at 1734. Secondary considerations such as commercial success, long felt but unsolved needs, or failure of others may also be persuasive.

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Only if this initial burden is met does the burden of coming forward with evidence or

argument shift to the appellant. *Id.* at 1445. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445. One criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success viewed in light of the prior art. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

"It remains important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does". *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). "Hindsight" is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at appellant's claimed invention has not been explained. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The claimed subject matter is nonobvious if it involves a number of complex and unpredictable alternatives and there is no reason one of skill in the art would select one alternative over another. *Ortho-McNeil vs. Mylan, Inc*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Applicants claim 21 is directed to a system for coordinating the onset and offset of two or more different electrical signals to electrodes implanted in tissue used to coordinately control a bone, sphincter, tissue, structure or cartilage movement in the hypopharynx, or upper airway to protect the airway, the system comprising: a controller with a stored program that directs a signal generator to send electrical pulses to each of at least two electrodes in a determined pattern, wherein the determined pattern of electrical pulses coordinates the onset and offset of two or more different electrical signals to the at least two electrodes to protect the airway, each signal sent to a different electrode implanted in the tissue, the implantable signal generator, at least two intramuscular electrodes suitable for implantation in a muscle in the hypopharynx, or upper airway, a switch located external to the body and configured to be activated by a human, wherein the switch is configured to communicate to the signal generator upon activation by the human, and a sensor device; wherein the controller under the direction of the stored program directs the signal

generator to coordinate the onset and offset of two or more different electrical signals to activate each of the intra-muscular electrodes to move the bone, sphincter, tissue, structure or cartilage.

Applicants claim 24 is directed to a system for moving a cartilage within a subject comprising: an implantable signal generator comprising a power source and a processor; a first electrode implantable in a first hyo-laryngeal muscle attached to the cartilage and operably connected to the signal generator; a second electrode implantable in a second different hyo-laryngeal muscle attached to the same cartilage and operably connected to the signal generator; and a switch located external to the body and configured to be activated by the subject, wherein the switch is configured to communicate to the signal generator upon activation by the subject; wherein the processor is configured to generate a signal of about 10 to 75 Hz to each of the first and second electrodes at the same time and to effect a swallow elevation and laryngeal movement velocity in the cartilage that exceeds the movements made by pulses sent to the muscles at separate times.

Applicants claim 28 is directed to a system for control of stimulation during swallowing of a human with dysphagia comprising: at least two intra-muscular electrodes; an implantable signal generator connected to the at least two electrodes and that comprises a processor configured to control the output energy to the electrodes according to a determined pattern, a controller with a stored program that directs the signal generator to send electrical pulses to each of the at least two electrodes in the determined pattern, wherein the determined pattern of electrical pulses comprises a frequency of about 10 to 75 Hz and moves at least two different muscles that control hyoid bone movement so that the hyoid bone moves up at least 80% of the elevation of a normal swallow; a power supply that provides energy for the signal generator; an implantable sensor configured to detect physiological movement; and a switch operable by the human that controls the signal generator, wherein the operation of the switch by the human activates the controller to direct the signal generator to send electrical pulses to each of the at least two electrodes in the determined pattern.

Applicants submit that the Examiner has not established a prima facie case of obviousness because the combination of the references does not disclose all of the elements of the claims and there would be no reasonable expectation of success. Applicants have also provided evidence of unexpected results.

The Freed et al patent is directed to a method of placing electrodes on the skin in order to stimulate the sensory nerves in the pharyngeal region and assist the patient with relearning to swallow. This method is noninvasive and does not involve the patient activating a switch to send a signal to stimulate movement. With respect to claim 21, this reference does not disclose a controller with a stored program that directs a signal generator to send electrical pulses to each of at least two electrodes in a determined pattern, wherein the determined pattern of electrical pulses coordinates the onset and offset of two or more different electrical signals to the at least two electrodes to protect the airway.

The deficiencies of this reference are not remedied by reference to Sanders. Sanders is directed to a method for opening an airway rather than for protecting an airway. Moreover, Sanders does not describe a controller or a controller with a stored program to coordinate the onset and offset of electrical pulses to protect the airway. Sanders does not describe coordinating the onset and offset of two or more signals in order to obtain coordinated movement to protect the airway. The onset and offset of electrical signals going to two different electrodes is not discussed at all.

With respect to claim 24, in the least, Freed does not disclose a switch operable by the human to control application of the signal or a processor configured to generate a signal of about 10 to 75 Hz to each of the first and second electrodes at the same time and to effect a swallow elevation and laryngeal movement velocity in the cartilage that exceeds the movements made by pulses sent to the muscles at separate times. The system of Freed is directed to continuous external stimulation of the tissue on the neck surface and would not be effective if it was controlled by the patient since the method of Freed depends on repeated sensory stimulation of peripheral nerves. The continuous external stimulation of Freed is directed to assisting the patient to relearn the swallowing motion. Moreover, Freed does not discuss that the processor is configured to deliver a signal to each of two electrodes that effects a swallow elevation and laryngeal movement velocity greater than the movements made by muscles receiving the signals at separate times.

The deficiencies of Freed are not remedied by reference to Sanders. Sanders is directed to opening the airway. The Sanders reference only describes a single muscle, the posterior cricoarytenoid muscle. When Sanders is read as a whole, it is directed to stimulation of a single

muscle that opens rather than closes the airway. The signal parameters described in Sanders relate to restoring normal respiration by opening of the airway. There is no discussion in this reference of a processor configured to generate a signal of about 10 to 75 Hz to each of the first and second electrodes at the same time and to effect a swallow elevation and laryngeal movement velocity in the cartilage that exceeds the movements made by pulses sent to the muscles at separate times. Swallow elevation and laryngeal movement velocity are not discussed at all since this actions result in closure rather than opening of the airway.

With respect to the claim 28, Applicants submit that the Freed patent does not teach or suggest a system comprising a controller that has a stored program that directs the signal generator to send electrical pulses to each of the at least two electrodes embedded in muscle in the determined pattern, wherein the determined pattern of electrical pulses comprises a frequency of about 10 to 75 Hz and moves at least two different muscles that control hyoid bone movement so that the hyoid bone moves up at least 80% of the elevation in a normal swallow. As discussed previously, the application of the surface stimulation applied by Freed moves the hyoid bone down.

Moreover, Freed does not teach or suggest a switch operable by the human to control application of the signal. The system of Freed is directed to continuous but uncoordinated external stimulation of the tissue on the throat that cannot reach the pharyngeal tissue and would not be effective if it was controlled by the patient. The continuous external stimulation of Freed does not benefit swallowing as it pulls the hyoid downward.

The deficiencies of Freed are not remedied by reference to Sanders. Sanders is directed to opening the airway. The Sanders reference only describes a single muscle, the posterior cricoarytenoid muscle. When Sanders is read as a whole, it is directed to stimulation of a single muscle that opens rather than closes the airway. The signal parameters described in Sanders relate to restoring normal respiration by opening of the airway. There is no discussion in this reference of a controller that has a stored program that directs the signal generator to send electrical pulses to each of the at least two electrodes embedded in muscle in the determined pattern, wherein the determined pattern of electrical pulses comprises a frequency of about 10 to 75 Hz and moves at least two different muscles that control hyoid bone movement so that the hyoid bone moves up at least 80% of the elevation in a normal swallow. Hyoid bone elevation

and signals that achieve hyoid elevation are not discussed at all since such elevation results in closure rather than opening of the airway.

Moreover, if one of skill in the art combined the teachings of Freed and Sanders, swallowing would be made worse as Sanders teaches stimulation of a single muscle in order to open the airway. Opening the airway during swallowing would lead to aspiration of the material being swallowed. In addition, one of skill in the art would not know which muscles should be coordinated in order to provide for swallowing, as Sanders only describes a single muscle and Freed only describes external placement over many muscles. Manual stimulation as described in Sanders could not be applied to the methods described in Freed as continuous stimulation is necessary in Freed while the patient is attempting to relearn the swallowing motion even though the movement induced by the Freed stimulation on the skin surface interferes with swallowing. The Examiner has presented no evidence that activation of a signal by the patient as described in Freed would be sufficient to result in swallowing.

The examiner has not established a reason as to why one of skill in the art would combine portions of the teachings of these two references especially since if such a combination of these references were made either the method of Freed would not function as intended (as pointed out above) or there would be insufficient direction as to the signal parameters that provide for coordination of the action of muscles to achieve protection of the airway. "Hindsight" is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at appellant's claimed invention has not been explained. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. There is no teaching or suggestion in the cited references as to which muscles should be targeted and the type of signals that would provide for coordinate control of at least two muscles to move the hyoid and larynx up so as to achieve protection of the airway and avoid aspiration.

The Examiner has also presented no evidence that there would be a reasonable expectation of success that the appropriate muscles would be targeted, and that the appropriate signal parameters would be applied based on the teachings of the cited references. Swallowing is a complex movement requiring the coordination of at least two muscles. The examiner has not

provided any evidence from the cited references that signals applied intramuscularly to at least two muscles would predictably result in swallowing. There are too many different variables that need to be changed from the combination of the cited references in order to achieve the claimed subject matter.

Applicants submit that they have also provided evidence of unexpected results. The unexpected results are that the muscles do not adapt to the signals even if the amount of stimulation applied is greater than would occur normally. Electrical stimulation of muscles could result in damage or alteration of the capacity of the muscles to contract. The results provided in the application show that the duration of mylohyoid and thyrohyoid muscle activity did not change after stimulation. See figure 8. In addition, the interval between mylohyoid onset and thyrohyoid onset did not change after 10 stimulation trials. See figure 10.

Secondly, it was unexpected that coordination of just two muscles provides 80% of the movement needed for the patient to swallow and prevents aspiration of the patient while swallowing. Swallowing is a complex movement requiring the coordination of at least two muscles. At least 12 muscles are involved in movement of the hyoid bone. It was unexpected that the coordination of just two muscles would be sufficient to raise the hyoid bone to protect the airway and open the esophageal sphincter. The device as claimed provides coordination of the movement driven by the application of electrical signals as directed by the stored program or by communication to the implantable stimulator. None of the cited reference discuss the coordination of muscle movement in this manner. In fact, as applicants have shown the application of signals to the skin as taught by Freed results in movement of the hyoid bone down rather than up.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 21 to 24, 26-29, 31, 33-35, and 44-47 under 35 U.S.C. § 103(a).

Summary

Applicants submit that the claims of the present application are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' representative at the telephone number listed below, if the Examiner believes that doing so will advance prosecution.

Respectfully submitted,

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